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(71) Applicant: E.R. Squibb & Sons, Inc.
Lawrenceville-Princeton Road
Princeton, N.J. 08540(US)

(72) Inventor: Ferguson, Keith T.
231 Katherine Street
Scoth Plains New Jersey(US)

(72) Inventor: Mcclees, Nancy J.
6953 MacGregor Court
Worthington Ohio(US)

(74) Representative: Cook, Anthony John et al,
D. YOUNG & CO. 10, Staple Inn
London, WC1V 7RD(GB)

(54) Wound care and drainage system.

(57) Pouch type wound care and drainage system wherein the pouch includes a bottom wall secured to an adhesive layer which can be cut to fit around the wound or surgical opening, gusseted side walls, and a top wall provided with one or more access openings. Means are provided for securing an irrigation port and a catheter access port to these top wall openings. The bottom wall extends beyond the adhesive layer and is provided with a large exit port oriented in such a manner that gravity will drain wound exudate from the pouch. This exit port is also large enough to accommodate the average size hand to aid in locating the pouch on the body and permit access to the wound site without removing the pouch from the body.

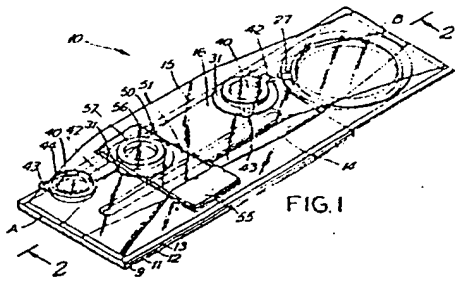

FIG. 1

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WOUND CARE AND DRAINAGE SYSTEM

This invention is directed to a pouch type wound care and drainage system. The pouch includes a bottom wall secured to an adhesive layer which can be cut to fit around the wound or surgical opening, gusseted side walls, and a top wall provided with one or more access openings. Means are provided for securing an irrigation port and a catheter access port to these top wall openings. Also, the bottom wall extends beyond the adhesive layer and is provided with a large exit port oriented in such a manner that gravity will drain wound exudate from the pouch. This exit port is also large enough to accomodate the average size hand to aid in locating the pouch on the body and permit access to the wound site without removing the pouch from the body.

Figure 1 is a perspective view of the wound care and drainage pouch of this invention;

Figure 2 is a sectional view taken along line 2-2 of Figure 1;

Figure 3 is a detailed view showing the catheter retainer as it would be attached to the wound drainage pouch; and

Figure 4 is an exploded view showing the irrigation port as it would be constructed and attached to the wound drainage pouch.

This invention is directed to a pouch type wound care and drainage system. The pouch 10 includes a bottom wall 13, a top wall 16 and gusseted side walls 14 and 15. Top wall 16 is joined to bottom 13 along edges A and B by heat sealing or other means. Preferably, the pouch walls are formed from an odor proof, moisture proof, flexible, transparent, polymeric film material such as polyethylene.

Pouch 10 includes a layer of medical grade pressure sensitive adhesive 11 for attaching the device to the body of the patient. Adhesive layer 11 can be attached directly to bottom pouch wall 13. Preferably, adhesive layer 11 includes a thin film 12 of water insoluble polymeric material such as polyethylene and bottom pouch wall 13 is attached to film 12 by an aggressive adhesive. The exposed bottom surface of adhesive 11 is covered by silicone coated release paper 9 until the pouch is to be applied.

Adhesive layer 11 is preferably a homogeneous blend of one or more water soluble or swellable hydrocolloids such as gelatin, pectin, guar gum, sodium carboxymethylcellulose, etc. dispersed in a viscous elastomeric binder such as polyisobutylene as described by Chen in United States Patent 3,339,546. Optionally, the adhesive layer can also include one or more cohesive strengthening

agents as described by Chen et al. in United States Patent 4,192,785.

As shown in Figures 1 and 2, bottom pouch wall 13 extends beyond adhesive 11. This extended portion of bottom wall 13 includes an aperture 19 whose functions will be described below. Flange 24 of a polymeric material such as polyethylene is heat sealed to bottom wall 13 around aperture 19. Flange 24 includes a coupling rib 25 that extends outwardly and perpendicularly from flange 24 and a hinge element 22 that is also connected to a cap 20. Cap 20 is also formed of a polymeric material such as polyethylene and includes a channel shaped coupling member 21 that is dimensioned to snap over coupling rib 25. Cap 20 also includes a pull tab 27 to aid in disengaging the coupling elements.

Top pouch wall 16 includes one or more apertures. In the embodiment shown in the figures, top pouch wall 16 has apertures 17 and 18. For ease of construction, apertures 17 and 18 are of identical size and are smaller than aperture 19 in the bottom pouch wall. A flange 31 of polymeric material such as polyethylne is heat sealed to top pouch wall 16 around apertures 17 and 18. Flange 31 includes an outwardly and perpendicularly extending coupling rib 32 and a hinge element 42 that is also connected to a cap 40. Cap 40 is also formed of

a polymeric material such as polyethylene and includes a channel shaped coupling member 44 that is dimensioned to snap over coupling rib 32. Cap 40 also includes a pull tab 43 to aid in disengaging the coupling elements.

Coupling ribs 25 and 32 preferably include thin, resilient, deflectible seal strips 26 and 33 which deform into a tight fit within channel shaped coupling members 21 and 44. As shown in Figure 2, the seal strip preferably extends inwardly from the rib shaped coupling members. However, the coupling system will also be effective if the seal strips extend outwardly from the ribs. Also, in order to increase the security of the seal, the surface of coupling ribs opposite the deflectible seal strip can include a peripheral rim that cooperates with a rim in the channel shaped coupling members. This type of coupling system is described in detail by Steer et al. in British Patent 1,571,657.

Apertures 17 and 18 permit treatment of the patient without the need for first removing and then reattaching the wound drainage device. For example, either or both of caps 40 can be detached and a catheter retaining means or wound irrigation means attached in its place.

Catheter retaining means 50 for use with the wound drainage device of this invention is shown in Figures 1 to 3. Means 50 consists of a flat tube shaped envelope 51 of polymeric film material such as polyethylene sealed along three edges and having an aperture 52 in one wall. A channel shaped coupling member 57 is heat sealed around aperture 52 and includes a pull tab 56. Channel shaped coupling element 57 is dimensioned to be a snap fit over coupling rib 32. Two strips 55 of polymeric foam such as closed cell polyurethane or polyethylene foam are each coated on one surface with an acrylic adhesive and are attached to the outer surfaces of envelope 51 at the unsealed edge. The foam strips 55 extend beyond the edge of envelope 51 and prior to use the exposed adhesive of the foam strips are covered with peelable release paper. In use, the release papers are removed and the foam strips can then be sealed tightly around a catheter 34 as shown in Figure 3.

Wound irrigation means 60 for use with the wound drainage device of this invention is shown in Figure 4. Means 60 consists of a channel shaped coupling member 62 including a pull tab 63. A disc 64 having an aperture 65 is heat sealed across the back of channel shaped coupling member 62. Element 66 having an upstanding port 67 and a plug type closure element 68 is heat sealed to disc 64 so that

port 67 aligns with aperture 65. Channel shaped member 62, disc member 64, and element 66 are formed from a compatible, heat sealable, polymeric material such as polyethylene. Channel shaped coupling member 62 is dimensioned to snap over rib 32. In use, a flexible tube from a source of irrigating fluid (not shown) would be squeezed over port 67. After the irrigation has been completed, the tube would be removed and port 67 would be sealed with plug 68.

The wound drainage and treatment device 10 of this invention is used by first cutting an opening through release paper 9, adhesive layer 11, polymeric film 12, and pouch bottom wall 13 somewhat larger that the wound itself. The release paper is then stripped away and the device is pressed firmly against the patient's body. Aperture 19 is large enough to permit insertion of an average sized hand and this aids in both the cutting and attaching steps. If needed, strips of medical grade adhesive tape can be employed to anchor the edges of the adhesive layer 11.

By keeping cap 20 and caps 40 in place a closed environment is maintained around the wound. When needed, either or both of caps 40 can be removed and replaced by the catheter retainer means or the wound irrigation means.

Aperture 19 serves several functions. In addition to being employed when the wound opening

is cut into the device, it provides ready access to the wound without the need for removing the device. Thus, the physician or nurse can reach through this aperture and perform any needed manipulation of the wound area.

Aperture 19 also serves as the exit port for material being drained from the wound. By locating aperture 19 in the bottom pouch wall, gravity can be employed to aid in the drainage operation regardless of whether the device is oriented on the body in a horizontal, vertical, or diagonal position.

Pouch 10 can be drained on an intermittent basis by holding a receptacle beneath aperture 19 and removing cap 20. By squeezing on pouch walls 14 and 15, even heavy fluids can be removed from the pouch. The pouch can also be drained on a continuous basis by removing cap 20 and employing a sleeve (not shown) having at one end a channel shaped coupling member sized to fit over rib 25 and which empties into a storage receptacle at the side of the bed.

The wound drainage device 10 of this invention can be made in various sizes for use with different types of wounds and surgical incisions. A typical size drainage device will have an adhesive layer 11 of about 30 cm. by 14 cm. and the bottom wall 13 will extend about another 15 cm. Aperture 19 will be about 10 cm. in diameter and apertures 17 and 18 will be about 4 cm in diameter.

What we claim is:

1. A wound care and drainage system comprising a pouch having a bottom wall, top wall, and gusseted side walls, said pouch walls formed from a transparent, moisture proof, odor proof, polymeric film material, a portion of said pouch bottom wall secured to an adhesive layer with the remainder of said pouch bottom wall extending beyond said adhesive layer, an aperture in said extended pouch bottom wall, and means encircling said bottom wall aperture whereby a cap can be detachably secured to seal said bottom wall aperture.

2. A wound care and drainage system as in Claim 1 wherein said pouch top wall includes one or more apertures and means encircling said top wall apertures whereby caps can be detachably secured to seal said top wall apertures.

3. A wound care and drainage system as in Claim 2 wherein flanges of polymeric material are sealed to said bottom pouch wall and said top pouch wall around said bottom wall aperture and said top wall apertures, said flanges have an outwardly and perpendicularly extending coupling rib shaped member, and caps of polymeric material are attached by a hinge to each of said flanges, said caps having a channel shaped coupling member dimensioned to snap over the coupling rib shaped member of the corresponding flange.

4. A wound care and drainage system as in Claim 3 wherein said coupling rib shaped members have a thin, resilient, deflectible seal strip which deforms into a tight fit within said channel shaped coupling members.

5. A wound care and drainage system as in Claim 4 wherein said seal strips extend inwardly from said coupling rib shaped members.

6. A wound care and drainage system as in Claim 4 wherein said seal strips extend outwardly from said coupling rib shaped members.

7. A wound care and drainage system as in Claim 3 wherein a catheter retaining means is detachably secured to one of said pouch top wall apertures.

8. A wound care and drainage system as in Claim 7 wherein said catheter retaining means comprises a flat envelope of polymeric material sealed along three edges and having an aperture in one wall of said envelope, a channel shaped coupling member secured to said envelope around said aperture, said channel shaped coupling member dimensioned to snap over the coupling rib shaped member projecting from the flange secured around said pouch top wall aperture, and strips of polymeric foam material secured to the surfaces of said envelope near the open end of said envelope, said strips of foam coated with an adhesive material so that the foam strips can be pressed into tight contact with a catheter.

9. A wound care and drainage system as in Claim 3 wherein a wound irrigation means is detachably secured to one of said pouch top wall apertures.

10. A wound care and drainage system as in Claim 9 wherein said wound irrigation means comprises a channel shaped coupling means dimensioned to snap over the coupling rib shaped member projecting from the flange secured around said pouch top wall aperture, a disc having an aperture secured across the back of said channel shaped coupling means, and an element having an upstanding port and a plug secured to said disc so that said port and said disc aperture are aligned.

11. A wound care and drainage system as in Claim 1 wherein said bottom wall aperture is about 10 cm. in diameter whereby an average sized hand can be inserted through said aperture into said pouch.

12. A wound care and drainage system as in Claim 2 wherein said pouch top wall has two apertures of approximately the same size.

13. A wound care and drainage system as in Claim 12 wherein the diameter of said bottom wall aperture is at least about twice the diameter of each of said top wall apertures.

14. A wound care and drainage system as in Claim 1 wherein said adhesive layer has a thin film of water insoluble polymeric material secured to one surface and said bottom pouch wall is secured to said thin polymeric film.

15. A wound care and drainage system as in Claim 14 wherein said pouch walls and said thin polymeric film are polyethylene.

16. A wound care and drainage system as in Claim 15 wherein said adhesive layer is a homogeneous blend of one or more water soluble or water swellable hydrocolloids dispersed in a viscous elastomeric binder.

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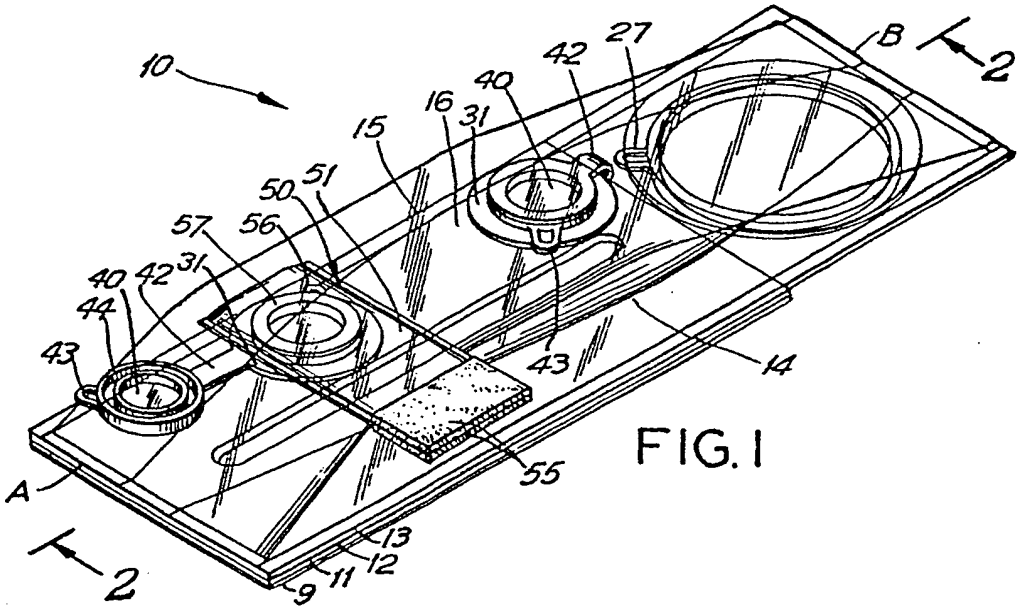


FIG. 1

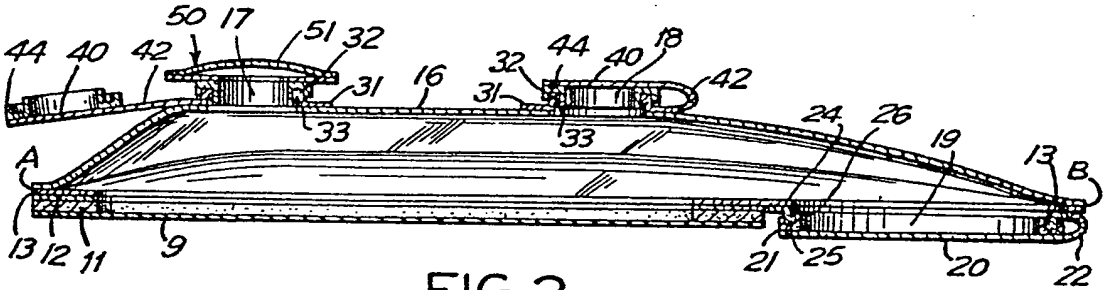


FIG. 2

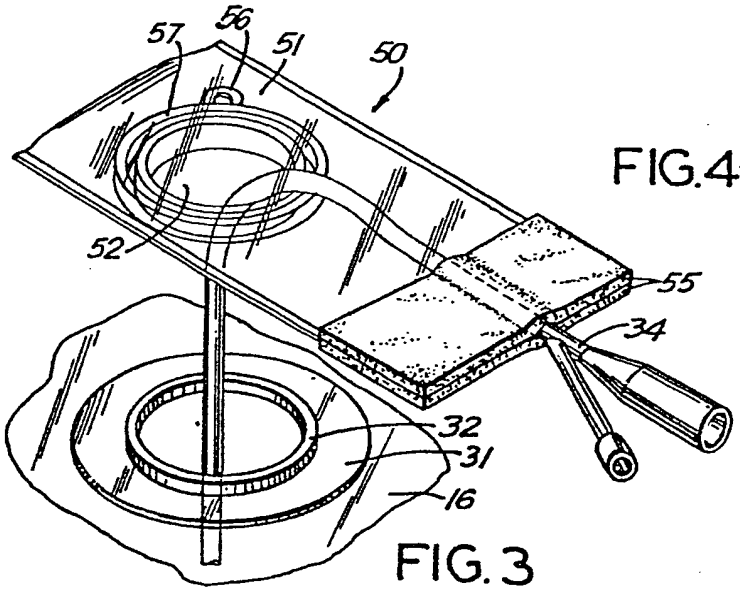
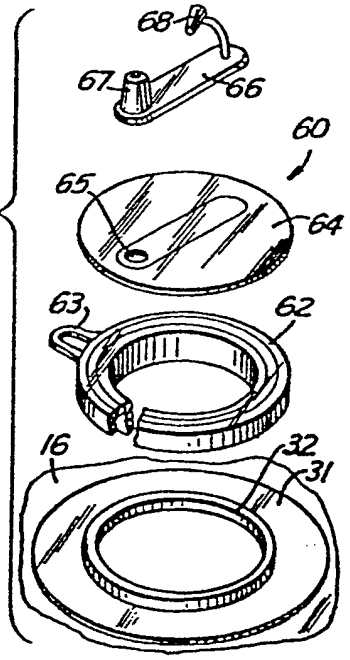


FIG. 3

FIG. 4



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EUROPEAN SEARCH REPORT

0142262
Application number

EP 84 30 6911

DOCUMENTS CONSIDERED TO BE RELEVANT

Category	Citation of document with indication, where appropriate, of relevant passages	Relevant to claim	CLASSIFICATION OF THE APPLICATION (Int. Cl.4)
A	GB-A-2 099 308 (HOLLISTER INC.) * Page 1, lines 93-125; figures 2, 3 *	1,2	A 61 M 1/00
A	FR-A-2 213 780 (HOWMEDICA INC.) * Figures 1, 5; revendications 1-3 *	1,2,15	
A	DE-A-2 442 087 (HOLLISTER INC.) * Page 3, last paragraph - page 4, paragraph 2; claim 1; figure 5 *	1,2	
A	US-A-2 928 393 (MARSAN) * Figures 1, 3, 5 *	1,7,9	
A	DE-A-2 236 455 (HOLLISTER INC.) * Claims 1, 2; figures 3, 7, 9 *	1,2	TECHNICAL FIELDS SEARCHED (Int. Cl.4)
A	GB-A-1 131 756 (HOLLISTER INC.) * Claim 1; figures 1-4 *	1,2,7, 9	A 61 M 1/00 A 61 M 27/00

The present search report has been drawn up for all claims

Place of search	Date of completion of the search	Examiner
BERLIN	09-01-1985	BARNY DE ROMANET P.M

CATEGORY OF CITED DOCUMENTS

X : particularly relevant if taken alone
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A : technological background
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E : earlier patent document, but published on, or after the filing date
D : document cited in the application
L : document cited for other reasons

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(71) Applicant(s)
David Ramon Gaunt
20 The Reddings, Red Road, BOREHAMWOOD, Hertfordshire, WD6 4SS, United Kingdom

Scott Glickman
Royal National Orthopaedic Hospital, Brockley Hill, Stanmore, Middlesex, HA7 4LP, United Kingdom

(72) Inventor(s)
David Ramon Gaunt
Scott Glickman

(74) Agent and/or Address for Service
Hyde, Heide & O'Donnell
10-12 Priests Bridge, LONDON, SW15 5JE, United Kingdom

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A61M 39/02 , A61B 17/34 , A61M 25/01

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A5R RAM REC RGB

(56) Documents Cited
WO 90/07311 A1 **US 5082005 A**

(58) Field of Search
UK CL (Edition M) **A5R RAM RAP RCE RGB RGD**
INT CL[5] **A61F 2/00 , A61M 25/00 25/04 39/00 39/02 39/04**
ONLINE DATABASES: WPI, MEDENG

(54) Organ access system and trocar assembly

(57) A medico-surgical system for access to a hollow viscus 4 includes a member (2, Fig. 1) adapted to extend through an opening in the skin into the viscus of the patient so that one end of the member is located within the viscus and the other end terminates adjacent the skin. Balloons 28 and 30 are provided for retaining the one end of the member within the viscus. The balloons 28 and 30 also act as sealing means, adapted to seal the opening whilst allowing intermittent access to the viscus 4, e.g. by means of a catheter 6.

Alternatively, the system comprises a tubular sleeve (92, Fig. 10), an inflatable cuff (94, Fig. 10) and a diaphragm (96, Fig. 10) having a self-sealing aperture.

A trocar assembly 70 has an inclined cutting surface 74 and a channel (78, Fig. 6) into which is slid a catheter 86.

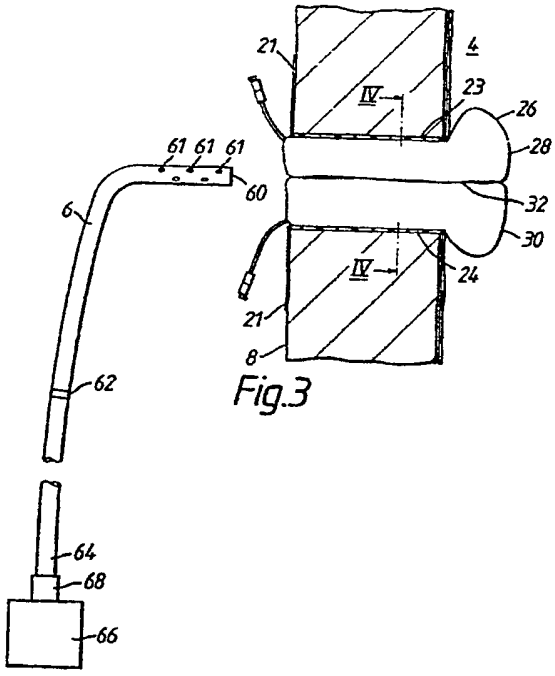

Fig.3

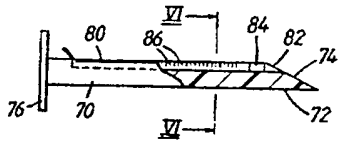

Fig.5

At least one drawing originally filed was informal and the print reproduced here is taken from a later filed formal copy.

The claims were filed later than the filing date within the period prescribed by Rule 25(1) of the Patents Rules 1990.

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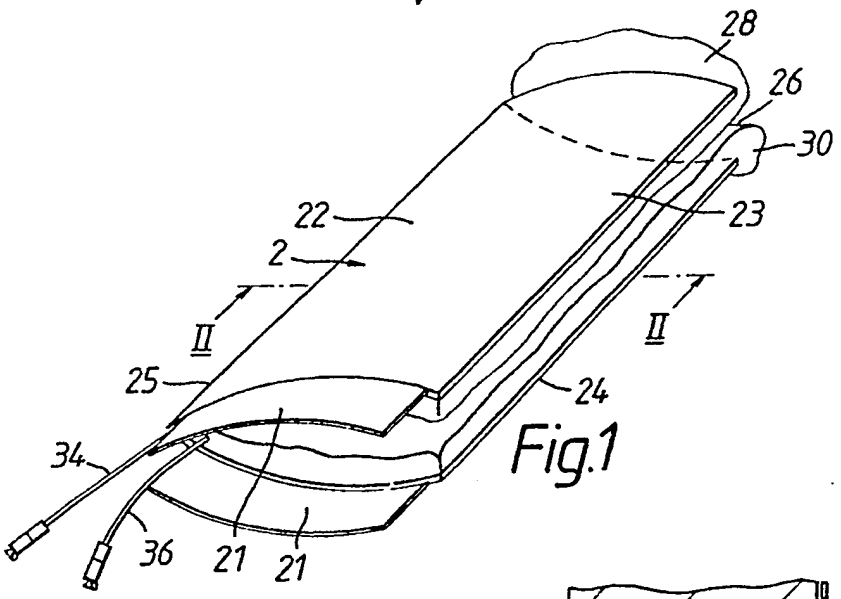


Fig.1

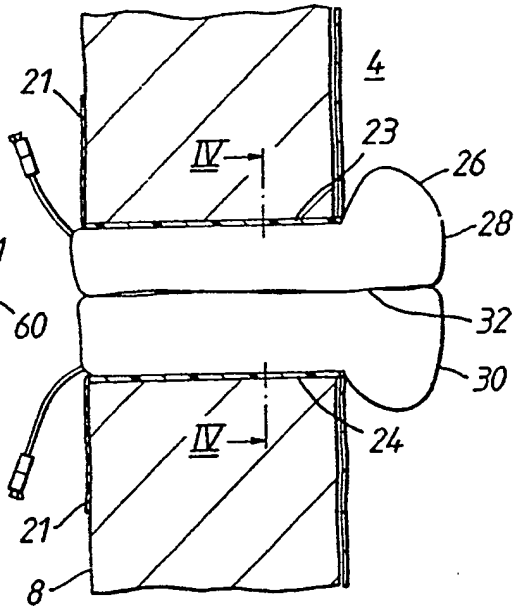
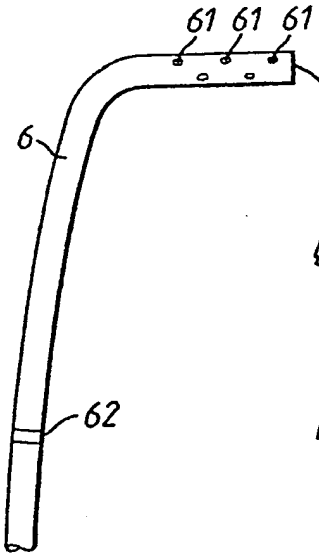
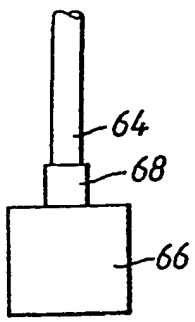


Fig.3





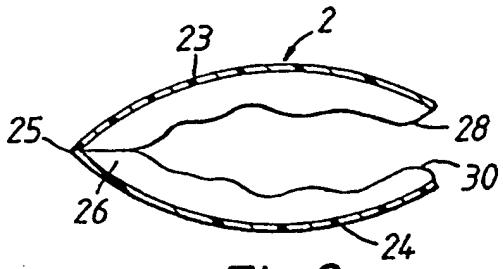


Fig.2

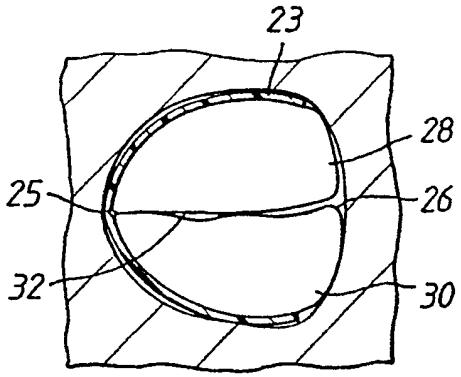


Fig.4

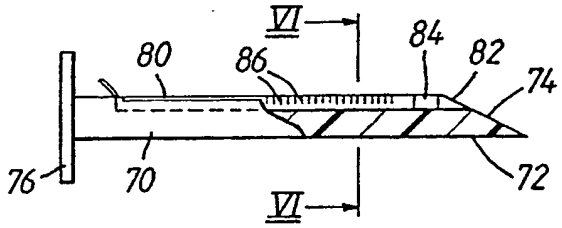


Fig.5

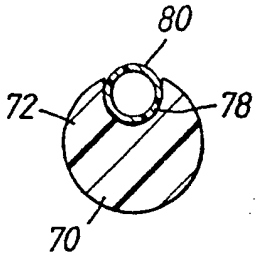


Fig.6

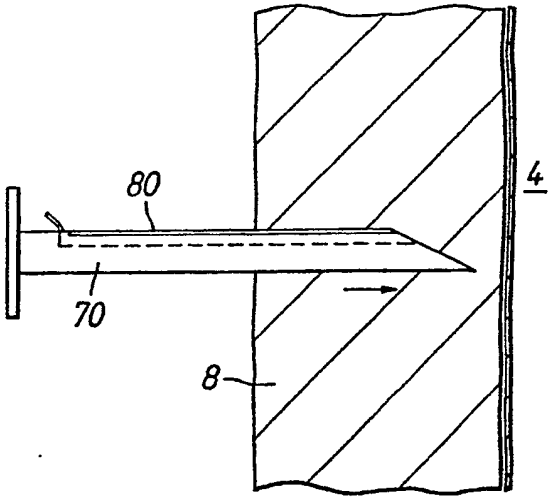


Fig.7

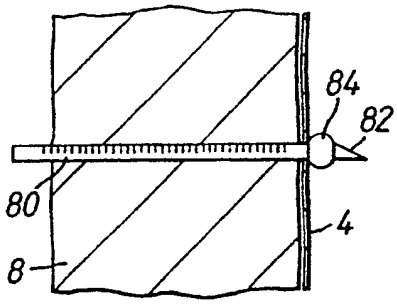


Fig.8

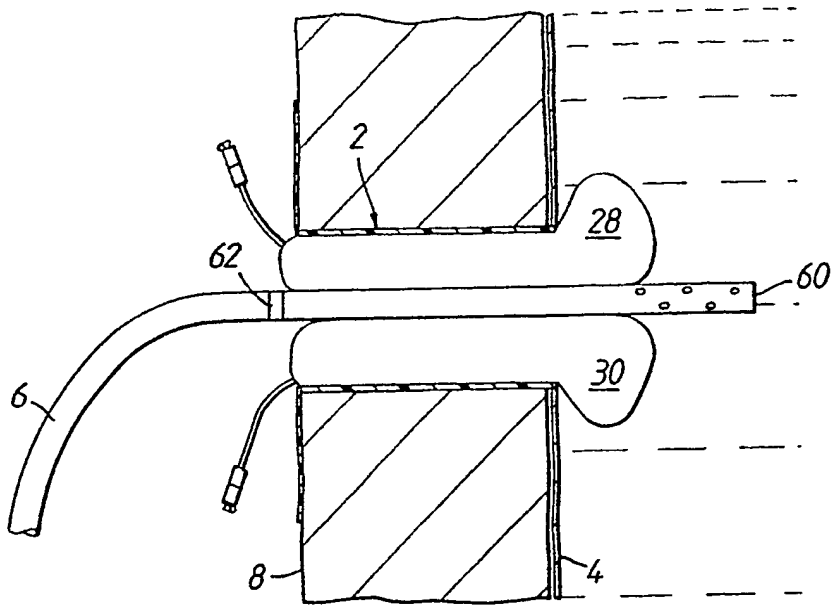


Fig.9

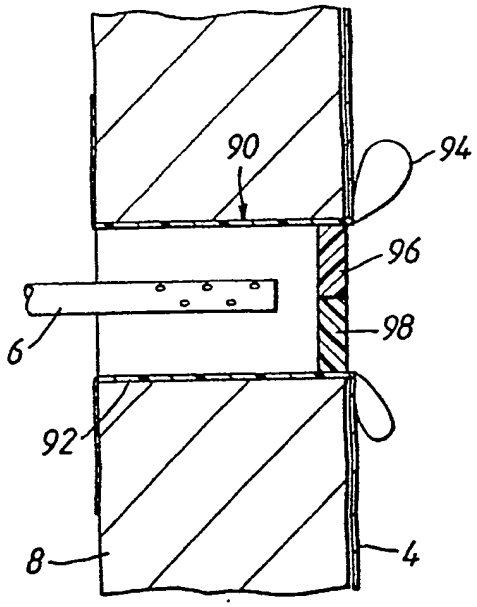


Fig.10

ORGAN ACCESS SYSTEMS AND TROCAR ASSEMBLIES

This invention relates to organ access systems and trocar assemblies.

The invention is more particularly, but not exclusively, concerned with bladder management systems.

In some clinical conditions, such as when nerve supply to the bladder is damaged, for example, after spinal trauma, it is necessary to drain the bladder artificially. Artificial drainage may also be necessary following surgery or when the genito-urinary system is blocked. This can be done by means of a catheter or the like inserted via the urethra. The disadvantage of this is that it can cause irritation, discomfort and infection. It can also lead to the formation of calculus and trauma causing strictures and false passages. Urethral incompetence can be a problem with women.

The catheter can be left in place to allow urine to drain continuously out of the bladder into a urine leg bag or the like. Alternatively, the catheter can be inserted intermittently to allow periodic emptying of the bladder. This has the advantages of reducing infection and of allowing the bladder to fill and empty in a way that more closely mimics normal physiology. It also

avoids the need to wear a drainage bag. There are, however, problems in repeatedly inserting a catheter into the urethra in that there is a repeated urethral trauma. Where the patient performs self catheterization, this can require manual dexterity and is often difficult and offensive to the patient. In cases where the patient retains urethral sensation, appreciable discomfort can be caused. There is also the risk of forcing urethral organisms into the bladder with each catheterization.

An alternative technique involves suprapubic catheterization in which a catheter extends into the bladder through a surgically-made opening in the abdominal wall. One end of the catheter is anchored in the bladder such as by means of an inflatable balloon or by coiling the end of the catheter. The other end of the catheter extends to a urine leg bag or similar receptacle so that urine can continuously drain away from the bladder. This suprapubic technique avoids trauma to the urethra but is still prone to infection and the accumulation of calculus. The technique also suffers from an additional problem in that it can be difficult to maintain the track into the bladder when the catheter is changed or if it should fall out. The risk that the track into the bladder may be lost means that replacement of the catheter is usually carried out in hospital rather than by nurses, patients or by their carers working in the community.

Examples of suprapubic catheter systems are described in US 3,640,281, US 3,924,633, US 3,860,006 and US 4,419,094.

There are other situations where access is required to a hollow organ or viscus such as where it is desired to supply fluid to the organ or where it is necessary to insert an endoscope.

It is one object of the present invention to provide an improved system for access to a hollow viscus.

According to one aspect of the present invention there is provided a medico-surgical system for access to a hollow viscus including a member adapted to extend through an opening in the skin into the hollow viscus of the patient so that one end of the member is located within the hollow viscus and the other end of the member terminates adjacent the skin, means for retaining the one end of the member within the hollow viscus, and sealing means adapted to seal the member whilst allowing intermittent access to the hollow viscus.

The system may be a bladder management system in which the one end of the member is located within the bladder and the other end of the member terminates adjacent the skin of the abdominal wall.

In this way, the bladder can be drained intermittently without the need for urethral catheterization. Furthermore, urine does not lie in the member, thereby reducing the build up of calculus. The sealing means also reduces the risk of infection.

The member may take the form of two leaves hinged together about a longitudinal edge and with their opposite longitudinal edge free.

The sealing means is preferably adapted to be opened by insertion of means within the member. The means insertable within the member is preferably a catheter through which urine flows out of the bladder. The sealing means may include a balloon member that normally effects the seal. Preferably, the seal is effected along substantially the entire length of the member. The means for retaining the member in the hollow viscus preferably also includes a balloon member.

It is another object of the present invention to provide an improved trocar assembly for use in making access to a hollow viscus.

According to the other aspect of the present invention there is provided a trocar assembly comprising a substantially rigid elongate trocar member having one end provided with an inclined, cutting surface adapted to penetrate body tissue, a channel extending along a major part at least of the length of the trocar member and opening at the one end of the trocar member, and a catheter removably located within the channel such that after penetration of a hollow viscus by the one end of the trocar, the catheter may be slid forwardly along the channel as the trocar is withdrawn to leave the catheter in position with one end in the hollow viscus.

Preferably, the channel opens along its length on a surface of the trocar. The catheter preferably has a locating cuff encircling it close to its one end by which the catheter can be retained in the hollow viscus.

Two bladder management systems according to the present invention will now be described, by way of example, with reference to the accompanying drawings, in which:

Figure 1 is a perspective side elevation view of a bladder management system deflated, prior to use;

Figure 2 is a transverse section along the line II - II of Figure 1;

Figure 3 is a side elevation view of the bladder management system inflated during use;

Figure 4 is a tranverse section along the line IV - IV of Figure 3;

Figure 5 is a partly cut-away side elevation view of a trocar used to install the bladder management system;

Figure 6 is a transverse section of the trocar along the line VI - VI of Figure 5, to an enlarged scale;

Figures 7 and 8 illustrate steps prior to insertion of the bladder management system;

Figure 9 is a sectional side elevation view of the bladder management system during drainage; and

Figure 10 is a sectional side elevation view of an alternative system.

With reference to Figures 1 to 4, the bladder management system comprises two parts namely, a sealing member or accessor 2 which extends into the bladder 4, and a catheter 6 by which the accessor can be opened to allow drainage of urine from the bladder.

The accessor 2 comprises an outer shell or member 22 formed by two elongate leaves 23 and 24 of a bendable plastics material which each are bowed across their width with their concave surfaces facing one another. The leaves 23 and 24 are hinged together along one edge 25, their opposite edges being free. In this respect, the leaves may be an integral one-piece construction with the hinge being formed by a region of reduced thickness. Typically, the shell 22 is about 50mm long with each leaf 23 and 24 being about 20mm wide. The length of the accessor 2 is such that it extends outwardly from the bladder 4 as far as the external, skin surface of the anterior abdominal wall 8 where it terminates. At their external ends, each leaf 23 and 24 has an annular flange 21, or tabs or the like, which are secured to the skin surface such as by means of an adhesive, for example, a karaya stoma wafer. The accessor 2 also includes a balloon assembly 26 within the shell 22 which comprises two elongate balloons 28 and 30 of oval section, or may be formed by a single balloon of U-shape. The use of two balloons is, however, preferred for safety reasons, each

balloon by itself being sufficient to retain the accessor in the bladder and preserve the track. The balloons 28 and 30 are of a thin, flexible plastics material being about 60mm long, that is, longer than the shell 22. At its, external, left-hand end, each balloon 28 and 30 terminates level with, and is attached to, the external end of a respective leaf 23 or 24. At its internal, right-hand end, each balloon 28 and 30 is attached to the internal end of a respective leaf 23 and 24 and projects from it. Along their length, on one side, the balloons 28 and 30 are joined together and to the hinged edge 25 of the two leaves 23 and 24. On the opposite side, the balloons 28 and 30 are joined to the free, longitudinal edge of a respective one of the leaves 23 and 24. When uninflated, as shown in Figures 1 and 2, the two leaves 23 and 24 lie relatively close together with most of the balloon assembly 26 enclosed between the leaves except for that part which protudes from the right-hand end. When inflated, as shown in Figures 3 and 4, the balloons 28 and 30 open apart the two leaves 23 and 24 into a part circular configuration. Inflation of the balloons 28 and 30 beyond the longitudinal edge of the leaves 23 and 24 is limited by contact of the balloons with the surrounding tissue, so that the overall section of the accessor 2 when installed is generally circular.

The internal end of the balloon assembly 26 bulges outwardly into the bladder 4 thereby retaining the accessor 2 in position.

Alternative means for retaining the internal end of the accessor in the bladder could be used. When inflated, the two ballons 28 and 30 contact each other along their entire length within the shell, thereby sealing the passage 32 into the bladder 4. An inflation line 34 and 36 extends from each balloon 28 and 30 for use in inflation and deflation. The inflation lines 34 and 36 may be provided with a valve and a cap for sealing the lines. The material forming the balloons 28 and 30 may itself be resilient so that it is stretched on inflation by a relatively high internal pressure; alternatively, the balloons may be of the low-pressure kind, being inflated, but not stretched, by the air within them. In a further alternative embodiment, the balloons could be filled with a resilient foam. Insertion and withdrawal would then be carried out by applying negative pressure to suck the wall of the balloons about their foam filling, thereby reducing their cross section.

The catheter 6, forming the second part of the system, is typically about 600mm long and has an external diameter of about 5mm. The catheter 6 is made of a bendable plastics material such as PVC. One end 60 of the catheter is open and has several aperture 61 in its wall spread over a distance of about 30mm from the open end. At about 90mm from the open end, the catheter is provided with a marker 62 or a stop such as a flange, to indicate the extent of insertion. Conventional catheters could be used for drainage. At its opposite end 64, the catheter is coupled to a conventional urine bottle 66 or other urine receptacle, such as by means of a coupling 68. Alternatively, the end 64 could be open and simply held over a w.c. pan or urinal when discharge of urine is desired.

The bladder management system may be installed by means of an introducer or trocar assembly 70 shown in Figures 5 and 6. The assembly 70 comprises a trocar 72 of a rigid perspex, or other material, which is of cylindrical shape and circular section having a bevelled cutting point 74 at one end and a handle 76 at its opposite end. Typically, the trocar is 200mm long and 15mm in diameter. Along one edge, the trocar has a channel 78 of part circular section which opens along the length of the trocar. Slid into the channel 78 is a catheter 80 of a rigid perspex, or other material, which

is about 150mm long and has a diameter of about 4mm. The opening of the channel 78 is narrower than its diameter so that the catheter 80 is retained in the trocar 72. The forward end of the catheter 80 has a bevelled tip 82 which aligns with the bevelled tip 74 of the trocar. An inflatable cuff 84 encircles the catheter close to its bevelled tip 82.

In use, with a full bladder, the tip 74 of the introducer assembly 70 is pushed through the skin and tissue 8 of the abdomen, as shown in Figure 7, and into the bladder 4. The extent of penetration can be monitored by observation of graduated markings 86 on the catheter. Penetration of the bladder 4 is readily apparent by the flow of urine out of the catheter. The trocar 72 is then pulled rearwardly out of the patient, leaving the catheter 80 in place. The cuff 84 on the catheter 80 is inflated as the trocar is removed so as to secure the catheter in the bladder 4, as shown in Figure 8. A sterile urine specimen can be collected during initial drainage of the bladder 4 through the catheter 80. The purpose of the catheter 80 is to maintain the initial track into the bladder and drain the bladder prior to insertion of the accessor. It also enables the length of the track between the bladder 4 and the skin 8 of the abdomen to be measured.

The accessor 2 is then inserted in its deflated state by opening the shell 22 slightly so that the catheter 80 can be placed between two leaves 23 and 24. The leaves are held together as the accessor 2 is slid along the outside of the catheter 80 until its patient end is located in the bladder 4. It will be appreciated that the size of opening made by the trocar assembly 70 is greater than the diameter of the catheter 80 so that there is room to accommodate the larger size of the accessor. The bowed shape of the leaves 23 and 24 increase its rigidity in the longitudinal direction enabling it to be slid without buckling against friction with the tissue. The accessor 2 is then inflated so that the balloons 28 and 30 secure it in the bladder 4 and seal with the outside of the catheter 80, confining any residual flow of urine to the catheter. The catheter 80 can then by removed by deflating its cuff 84 and pulling it out between the balloons 28 and 30 which seal together behind it. Alternatively, an expansible dilator or a series of increasingly larger dilators could be slid alongside the catheter 80 and the track dilated to allow subsequent insertion of the accessor.

Once in position, with the balloons 28 and 30 inflated, the accessor 2 prevents flow of urine out of the bladder 4. When it is desired to empty the bladder, the catheter 6 is pushed into the accessor 2 along the passage 32 between the two balloons 28 and 30 until the marker 62 lies level with the external end of the accessor, or until urine starts to flow through the catheter within the accessor as shown in Figure 9. The balloons 28 and 30 in the accessor 2 seal with the outside of the catheter 6 and prevent urine seeping between the catheter and the accessor.

It can be seen that the bladder management system has several advantages. Firstly, because the bladder is drained intermittently rather than continuously, the user does not need to wear a leg bag. Secondly, the user can drain urine himself, as and when he wishes, without the need for assistance. There is no need for urethral catheterization, thereby avoiding the discomfort, trauma and the attendant risk of ascending infection. Furthermore, there is no risk of blockage caused by the build-up of calculus, because the catheter along which the urine is discharged is clean before each insertion through the accessor.

A very important advantage of the accessor is that replacement is relatively easy and presents no significant risk of the loss of track as compared with previous suprapubic catheters. Replacement is carried out by deflating slightly the balloon assembly of the original accessor whilst retaining sufficient air in the right-hand end of the balloons to provide continued retention. The replacement accessor, in a deflated condition, is pushed between the two leaves of the original accessor until its external end is level with that of the original accessor. The replacement accessor is now inflated and the original accessor deflated. The original accessor is then pulled out of the body along the outside of the replacement accessor.

The accessor is not confined to use with bladder management but could be used in any application where access is required to a hollow viscus or organ. For example, it could be used to provide a site for intermittent administration of fluid or medicament to a viscus via a tube inserted through the accessor. Alternatively, it could be used to enable access of an endoscope or a surgical instrument.

The trocar assembly also has applications other than in making access to a bladder.

It will be appreciated that the accessor could take various different forms. For example, the accessor could be of tubular form with two internal, D-shape balloons. Such a configuration would, however, be more difficult to replace than the accessor described above. In another example, shown in Figure 10, the accessor 90 has a tubular sleeve 92, that provides the track between the bladder 4 and the skin wall 8, and an inflatable cuff 94 which locates the accessor within the bladder. Instead of sealing the accessor by means of inflated balloons, a resilient diaphragm 96 is located close to the internal end of the accessor which has a self-sealing central aperture 98. When the catheter 6 is inserted, it extends through the aperture 98, the diaphragm 96 forming a wiping seal with the outside of the catheter. When the catheter is withdrawn, the aperture 98 resumes its sealed, closed state. Again, this accessor would be more difficult to replace, it would also retain more urine within it than the balloon accessor.

Although it is preferable that urine flows along a catheter inserted in the accessor, it could flow through the accessor itself, if the seal were opened by some means such as a rod or by partial deflation of the balloons. In this case, the accessor would need to be coupled at the skin surface to a receptacle. This alternative technique is probably only of practical use in emergency situations.

CLAIMS

1. A medico-surgical system for access to a hollow viscus including a member adapted to extend through an opening in the skin into the hollow viscus of the patient so that one end of the member is located within the hollow viscus and the other end of the member terminates adjacent the skin, means for retaining the one end of the member within the hollow viscus, and sealing means adapted the seal the member whilst allowing intermittent access to the hollow viscus.

2. A medico-surgical system according to claim 1, which is a bladder management system in which one end of the member is located within the bladder and the other end of the member terminates adjacent the skin of the abdominal wall.

3. A medico-surgical system according to claim 1 or 2, wherein the member takes the form of two leaves hinged together about a longitudinal edge with their opposite longitudinal edge free.

4. A medico-surgical system according to any preceding claim, wherein the sealing means is adapted to be opened by insertion of means within the member.

5. A medico-surgical system according to claim 4, wherein the means insertable within the member is a catheter.

6. A medico-surgical system according to any preceding claim, wherein the sealing means includes a balloon member.

7. A medico-surgical system according to any preceding claim, wherein the seal is effected along substantially the entire length of the member.

8. A medico-surgical system according to any preceding claim, wherein the means for retaining the member in the hollow viscus includes a balloon member.

9. A trocar assembly comprising a substantially rigid elongate trocar member having one end provided with an inclined cutting surface, adapted to penetrate body tissue, a channel extending along a major part at least of the length of the trocar member and opening at one end of the trocar member, and a catheter removably located within the channel such that after penetration of a hollow viscus by one end of the trocar, the catheter may be slid forward along the channel as the trocar is withdrawn to leave the catheter in position with one end in the hollow viscus.

10. A trocar assembly according to claim 9, wherein the channel opens along its length on a surface of the trocar.

11. A trocar assembly according to claim 9 or 10, wherein the catheter has a locating cuff encircling it close to its one end by which the catheter can be retained in the hollow viscus.

12. An organ access system substantially as herein described with reference to the accompanying drawings.

13. A trocar assembly substantially as herein described with reference to the accompanying drawings.

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Relevant Technical Fields (i) UK Cl (Ed.M) A5R (RAM, RAP, RCE, RGB, RGD) (ii) Int Cl (Ed.5) A61F 2/00; A61M 25/00, 25/04, 39/00, 39/02, 39/04 Databases (see below) (i) UK Patent Office collections of GB, EP, WO and US patent specifications. (ii) ONLINE DATABASES: WPI, MEDENG	Search Examiner MISS M M KELMAN Date of completion of Search 25 APRIL 1994 Documents considered relevant following a search in respect of Claims :- 1 to 8 and 12

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Category	Identity of document and relevant passages		Relevant to claim(s)
X	WO 90/07311 A1	(BUKH MEDITEC) see the Figures	1
X	US 5082005 A	(KALDANY) see the Figures	1,4,5,7

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